

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER BTG0005-100 (143593US01) - U.S. APPLICATION 10/510,370
INTERNATIONAL APPLICATION NO. PCT/GB03/01512	INTERNATIONAL FILING DATE 04 April 2003 (04.04.2003)	PRIORITY DATE CLAIMED 05 April 2002 (04.05.2002)
TITLE OF INVENTION LOW-DOSE POTASSIUM SUPPLEMENTATION FOR THE PREVENTION AND TREATMENT OF HYPERTENSION		
APPLICANT(S) FOR DO/EO/US Donald Johnstone Naismith and Alessandro Braschi		Express Mail Label No: EV514684935US Date of Deposit: AUGUST 10, 2005

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

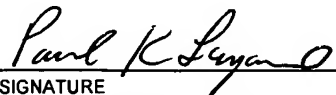
1. ☐ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☒ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☐ The US has been elected (Article 31).
5. ☐ A copy of the International Application as filed (35 U.S.C. 371(c)(2))
 - a. ☐ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)).
 - a. ☐ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☐ A preliminary amendment.
14. ☐ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821- 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: Forms PTO SB/08a and SB/08b (4 pp.); (37) References Cited and (36) References Enclosed; Copy of International Search Report dated August 6, 2003 for International Application No. PCT/GB03/01512.

This collection of information is required by 37 CFR 1.414 and 1.491-1.492. The information is required to obtain or retain a benefit by the public, which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 15 minutes to complete, including gathering information, preparing, and submitting the completed form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop PCT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

EV514684935US

U.S. APPLICATION NO. 10/510,370		INTERNATIONAL APPLICATION NO. PCT/GB03/01512		ATTORNEY'S DOCKET NUMBER BTG0005-100 (143593US01)	
The following fees are submitted:				CALCULATIONS	PTO USE ONLY
21. <input type="checkbox"/> Basic national fee\$300				\$	
22. <input type="checkbox"/> Examination fee					
If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)\$100				\$	
All other situations.....\$200					
23. <input type="checkbox"/> Search fee					
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority\$100					
International Search Report prepared and provided to the Office\$400				\$	
All other situations.....\$500					
TOTAL OF 21, 22 and 23 =				\$	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra sheet	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
- 100 =	/50 =		x \$250	\$	
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	\$	
Total claims	- 20 =		x \$50	\$	
Independent claims	- 3 =		x \$200	\$	
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			+ \$360	\$	
TOTAL OF ABOVE CALCULATIONS =				\$	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.					
SUBTOTAL=				\$	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				+	\$
TOTAL NATIONAL FEE =				\$	
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+	\$
TOTAL FEES ENCLOSED =				\$	
				Amount to be refunded:	\$
				Amount to be charged	\$
<p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit to Account No. <u>50-1275</u>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p>NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the International Application to pending status.</p> <p>SEND ALL CORRESPONDENCE TO:</p>					
Cozen O'Connor			 SIGNATURE		
1900 Market Street			Paul K. Legaard, Ph.D. NAME		
Philadelphia, PA 19103			38,534 REGISTRATION NUMBER		

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: **Naismith and Braschi**

Serial No.: **10/510,370**

Group Art Unit: **To Be Determined**

Filing Date: **May 9, 2005**

Examiner: **To Be Determined**

For: **LOW-DOSE POTASSIUM SUPPLEMENTATION FOR THE PREVENTION
AND TREATMENT OF HYPERTENSION**

EXPRESS MAIL INFORMATION

Express Mail Label No: EV514684935US

Date of Deposit: **AUGUST 10, 2005**

MAIL STOP AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §§ 1.56 and in accordance with 37 C.F.R. §§ 1.97 and 1.98, information relating to the above-identified application is hereby disclosed, the Examiner in charge of the above-identified application is requested to consider and make of record the references listed on the PTO Forms SB/08A and SB/08B, formerly known as PTO Form 1449 submitted herewith.

Inclusion of the information submitted herewith is not to be construed as an admission that the information is material as that term is defined in 37 C.F.R. § 1.56(b).

In accordance with 37 C.F.R. § 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.

This Information Disclosure Statement is being filed:

- ☐ within three months of the filing date of the patent application.
- ☐ within three months of the date of entry into the national stage as set forth in 37 C.F.R. § 1.491 of the international application.
- ☒ **before the mailing date of a first Office Action on the merits.**

- ☐ **after** the mailing date of a first Office Action on the merits, but before the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, and accordingly is accompanied by:
- ☐ the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below);
- or**
- ☐ the Fee of \$180.00 set forth in 37 C.F.R. § 1.17(p); or
- ☐ No fee is owed by the applicant(s).
- ☐ In accordance with 37 C.F.R. § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e) (see "Statement" below) and the fee of \$180.00 as set forth in 37 C.F.R. § 1.17(p), is attached.
- ☐ **after** the mailing date of a Final Office Action under 37 C.F.R. § 1.116 or a Notice of Allowance under 37 C.F.R. § 1.311, but before the payment of the Issue Fee, and accordingly is accompanied by the Statement under 37 C.F.R. § 1.97(e), (see "Statement," and "Fees" below).
- ☒ Copies of the references listed on the attached PTO Forms SB/08A and SB/08B, formerly known as PTO Form 1449 are enclosed. A copy of the International Search Report dated August 6, 2003 for International Application No. PCT/GB2003/01512, is enclosed.

EXCEPT THAT:

- ☐ In view of the voluminous nature of reference @, and the likelihood that this reference is available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with 37 C.F.R. § 1.98(d), copies of the references A-J listed on the attached PTO Form SB/08A, formerly known as PTO Form 1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) _____ for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application.

- JC20 Rec'd PCT/PTO 10 AUG 2005
- ☐ If any of the foregoing publications are not available to the Examiner,
Applicant will endeavor to supply copies at the Examiner's request.

Statement under 37 C.F.R. § 1.97(e)

- ☐ The undersigned attorney hereby states that each item information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign patent application not more than three months prior to the filing of the Information Disclosure Statement.

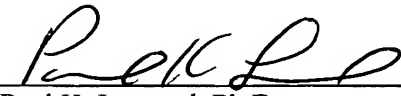
Fees

- ☒ No Fee is owed by the applicant(s).
- ☐ The Information Disclosure Statement Fee of \$180.00 under 37 C.F.R. § 1.17(p) is enclosed herewith.

Method of Payment of Fees

- ☐ Attached is a check in the amount of \$_____. This form is submitted in duplicate.
- ☐ Charge Deposit Account No. 50-1275 in the amount of \$180.00. This form is submitted in duplicate.
- ☒ Please charge any deficiency or credit any overpayment to Deposit Account 50-1275.
- ☐ No fee or Statement is required under 37 C.F.R. § 1.97(b).

Respectfully submitted,



Paul K. Legaard, Ph.D.
Registration No. 38,534

Dated: 10 AUGUST 2005

COZEN O'CONNOR, P.C.
1900 Market Street, 5th Floor
Philadelphia, PA 19103-3508
(215) 665-2000 – Telephone
(215) 701-2013 - Facsimile

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Substitute for form 1449B/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 4

Application Number	10/510,370
Filing Date	May 9, 2005
First Named Inventor	Donald Johnstone Naismith
Art Unit	To Be Determined
Examiner Name	To Be Determined
Attorney Docket Number	BTG0005-100 (143593US01)

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AF	Appel et al., "A clinical trial of the effects of dietary patterns on blood pressure," <i>N. Engl. J. Med.</i> , (1997) 336:1117-1124.	
	AG	Bates et al., "Micronutrients: highlights and research challenges from the 1994-5 National Diet and Nutrition Survey of people aged 65 years and over," <i>Br. J. Nutr.</i> (1999) 82:7-15.	
	AH	Boegehold et al., "Importance of Dietary Chloride for Salt Sensitivity of Blood Pressure," <i>Hypertension</i> (1991) 17(1 Suppl):158-161.	
	AI	Cappuccio et al., "Does potassium supplementation lower blood pressure? A meta-analysis of published trials," <i>J. Hypertens.</i> (1991) 9:465-473.	
	AJ	Dyer et al., "Body mass index and associations of sodium and potassium with blood pressure in INTERSALT," <i>Hypertension</i> (1994) 23:729-736.	
	AK	Freedman et al., "Salt and blood pressure. Conventional wisdom reconsidered," <i>Eval. Rev.</i> (2001) 25:267-287.	
	AL	Frisancho et al., "Blood pressure in blacks and whites and its relationship to dietary sodium and potassium intake," <i>J. Chronic. Dis.</i> (1984) 37:515-519.	
	AM	Geleijnse et al., "Sodium and potassium intake and blood pressure change in childhood," <i>Brit. Med. J.</i> (1990) 300:899-902.	
	AN	Giaconi et al., "Seasonal influences on blood pressure in high normal to mild hypertensive range," <i>Hypertension</i> (1989) 14:22-27.	
	AO	Graudal et al., "Effects of sodium restriction on blood pressure, renin, aldosterone, catecholamines, cholesterol, and triglyceride: a meta-analysis," <i>J. Amer. Med. Assoc.</i> (1998) 279:1383-1391.	
	AP	Gregory et al., <i>The Dietary and Nutritional Survey of British Adults</i> , HMSO London (1990) 154-158.	

Examiner
SignatureDate
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449B/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 3 of 4

Complete if ☒

Application Number	10/510,370
Filing Date	May 9, 2005
First Named Inventor	Donald Johnstone Naismith
Art Unit	To Be Determined
Examiner Name	To Be Determined
Attorney Docket Number	BTG0005-100 (143593US01)

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	AQ	Jansen et al., "The effect of a change in ambient temperature on blood pressure in normotensives," <i>J. Hum. Hypertens.</i> (2001) 15:113-117.	
	AR	Kannel, "Blood pressure as a cardiovascular risk factor: prevention and treatment," <i>J. Amer. Med. Assoc.</i> (1996) 275:1571-1576.	
	AS	Kawano et al., "Effects of potassium supplementation on office, home and 24-H blood pressure in patients with essential hypertension," <i>Am. J. Hypertens.</i> (1998) 10(11):1141-1146.	
	AT	Koneth et al., "Potassium and Arterial Hypertension - are Potassium Supplements Useful?" <i>Schweizerische Rundschau Fuer Medizin Praxis</i> (2000) 38(89):1499-1505. (German).	
	AU	Kotchen et al., "Dietary sodium and blood pressure: interactions with other nutrients," <i>Am. J. Clin. Nutr.</i> (1997) 65(2Suppl):708S-711S.	
	AV	Langford, "Dietary potassium and hypertension: epidemiologic data," <i>Ann. Intern. Med.</i> (1983) 98:770-772.	
	AW	Materson et al., "Single-drug therapy for hypertension in men. A comparison of six antihypertensive agents with placebo," <i>N. Engl. J. Med.</i> (1993) 328:914-921.	
	AX	Matlou et al., "Potassium supplementation in blacks with mild to moderate essential hypertension," <i>J. Hypertens.</i> (1986) 4:61-64.	
	AY	Morris et al., "Normotensive salt sensitivity: effects of race and dietary potassium," <i>Hypertension</i> (1999) 33:18-23.	
	AZ	Sacks et al., "Low blood pressure in vegetarians: effects of specific foods and nutrients," <i>Am. J. Clin. Nutr.</i> (1988) 48(3 Suppl):795-800.	
	BA	Sacks et al., "Effects on blood pressure of reduced dietary sodium and the Dietary Approaches to Stop Hypertension (DASH) diet," <i>N. Engl. J. Med.</i> (2001) 344:3-10.	

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 4 of 4

Complete if Known

Application Number	107510310
Filing Date	May 9, 2005
First Named Inventor	Donald Johnstone Naismith
Art Unit	To Be Determined
Examiner Name	To Be Determined
Attorney Docket Number	BTG0005-100 (143593US01)

NON PATENT LITERATURE DOCUMENTS

Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	BB	Shore et al., "A randomized crossover study to compare the blood pressure response to sodium loading with and without chloride in patients with essential hypertension," <i>J. Hypertens.</i> (1988) 6:613-617.	
	BC	Siani et al., "Controlled trial of long term oral potassium supplements in patients with mild hypertension," <i>Br. Med. J. (Clin. Res. Ed.)</i> (1987) 294:1453-1456. Double check author's name	
	BD	Sinaiko et al., "Effect of low sodium diet or potassium supplementation on adolescent blood pressure," <i>Hypertension</i> (1993) 21:989-994.	
	BE	Smith et al., "Socio-economic differentials in health: the role of nutrition," <i>Proc. Nutr. Soc.</i> (1997) 56:75-90.	
	BF	Rouse et al., "Blood-pressure-lowering effect of a vegetarian diet: controlled trial in normotensive subjects," <i>Lancet</i> (1983) 1:5-10.	
	BG	Ward et al., "Tokelau Island Migrant Study," <i>Hypertension</i> (1980) 2(Suppl. 1):43-54.	
	BH	Watanabe et al., "Potassium and Hypertension," <i>Nutrition Reviews</i> (1998) 5 (Part 1, No. 56):151-153.	
	BI	Whelton, "Epidemiology of hypertension," <i>Lancet</i> (1994) 344:101-106.	
	BJ	Whelton et al., "Effects of oral potassium on blood pressure. Meta-analysis of randomized controlled clinical trials," <i>J. Amer. Med. Assoc.</i> (1997) 277:1624-1632.	
	BK	Wilson et al., "Effects of potassium on blood pressure in salt-sensitive and salt-resistant black adolescents," <i>Hypertension</i> (1999) 34:181-186.	
	BL	International Search Report dated August 6, 2003 for International Application No. PCT/GB03/01512.	

Examiner
Signature

Date
Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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